IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SIGHT SCIENCES, INC., Plaintiff, v. IVANTIS, INC., ALCON RESEARCH LLC, ALCON VISION, LLC AND ALCON INC., Defendants.	)	C. A. No.: 21-1317-GBW-SRF **JURY TRIAL DEMANDED** [redacted] **Redacted - Public Version Filed on: October 23, 2023**

SIGHT SCIENCES, INC.'S OPENING BRIEF IN SUPPORT OF ITS MOTIONS FOR SUMMARY JUDGMENT AND TO EXCLUDE EXPERT TESTIMONY

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TABLE OF CONTENTS

Page(s)

TABLE OF CONTENTS
continued

Page(s)

TABLE OF CONTENTS
continued

Page(s)

TABLE OF ABBREVIATIONS

Document/Item	Abbreviation
U.S. Patent No. 8,287,482 (D.I. 1-1, Ex. A)	"'482"
U.S. Patent No. 9,370,443 (D.I. 1-1, Ex. B)	"'443"
U.S. Patent No. 9,486,361 (D.I. 1-1, Ex. C)	"'361"
U.S. Patent No. 10,314,742 (D.I. 1-1, Ex. D)	"'742"
U.S. Patent No. 11,389,328 (D.I. 59, Ex. E)	"'328"
U.S. Patent No. 8,287,482	"'482"
U.S. Patent No. 9,370,443	"'443"
U.S. Patent No. 9,486,361	"'361"
U.S. Patent No. 10,314,742	"'742"
U.S. Patent No. 11,389,328	"'328"
9/15/2022 Defendants' Answer to Second Amended Complaint, D.I. 77	"Answer to SAC"
U.S. Patent Nos. 8,287,482; 9,370,443; 9,486,361; and 10,314,742; and 11,389,328	"Asserted Patents"
Claims 1, 5, 7-8, 10-11, 15, 18, 21, 23, 32, 36, 38-39, 41-42, 46, 49, 52, 54, 63, 68-70, 73, 77, 79-80 of U.S. Patent No. 8,287,482; claims 1, 8, 11-12, 21, 23-24, 27, 42-43, 46, 52, 54-59, and 70-71 of U.S. Patent No. 9,370,443; claims 1-3 and 5-9 of U.S. Patent No. 9,486,361; claims 1-3, 6-9, 12-13, 15, 17-20 of U.S. Patent No. 10,314,742; and claims 1-2, 4-8, 12-14, 18, 21-23, 25-26 of U.S. Patent No. 11,389,328	"Asserted Claims"
9/18/2019 Transcript of Deposition of Todd Abraham in *Glaukos Corp. v. Ivantis, Inc.*, Case No. 8:18-cv-00620-JVS-JDE (C.D. Cal.)	"Abraham *Glaukos* Tr."
Bahler et al., "Trabecular Bypass Stents Decrease Intraocular Pressure in Cultured Human Anterior Segments," AMERICAN JOURNAL OF OPHTHALMOLOGY (Dec. 2004) (IVANTIS_SS_000014121-1429)	"Bahler"
9/20/2023 Transcript of Deposition of Karen Becker, Ph.D., Defendants' FDA Regulatory Expert	"Becker Tr."
8/17/2023 Expert Report of Karen Becker, Ph.D.	"Becker Rpt."
9/28/2023 Transcript of Deposition of J. Crawford Downs, Ph.D., Sight Sciences' Expert Witness on Infringement	"Downs Tr."
7/13/2023 Opening Expert Report of Dr. J. Crawford Downs on Infringement of U.S. Patent Nos. 8,287,482; 9,370,443; 9,486,361; 10,314,742; and 11,389,328	"Downs Op."
9/7/2023 Reply Expert Report of Dr. J. Crawford Downs on Infringement of U.S. Patent Nos.	"Downs Reply"

TABLE OF ABREVIATION
continued

Document/Item	Abbreviation
8,287,482; 9,370,443; 9,486,361; 10,314,742; and 11,389,328	
Exhibits attached to the Declaration of Lauren Strosnick In Support of Sight Sciences. Inc.'s Omnibus Opening Brief In Support of Motions Under Rule 56 and Motions to Exclude Expert Testimony	"Ex."
U.S. Food and Drug Administration	"FDA"
10/6/2022 Ivantis's Corrected First Supplemental Initial Invalidity Contentions	"First Suppl. Invalidity Contentions"
7/13/2023 Opening Expert Report of Dr. John Galanis, Sight Sciences' Expert Witness on Infringement of U.S. Patent Nos. 9,486,361; 10,314,742; and 11,389,328	"Galanis Op."
5/31/2023 Transcript of Deposition of Ahmad Hadba, Defendants' witness designated on Sight Sciences' Rule 30(b)(6) Topics 5, 9, 15, 28, 30, 61, and 63	"Hadba Tr."
Hydrus® Microstent, the accused product	"Hydrus"
9/2/2022 Ivantis's Corrected Initial Invalidity Contentions	"Initial Invalidity Contentions"
Third Party Glaukos's intraocular device, which Defendants assert is prior art	"iStent"
iStent Directions for Use	"iStent DFU"
9/14/2023 Transcript of Deposition of Andrew G. Iwach, M.D., Defendants' Expert Witness on Non-Infringement	"Iwach Tr."
8/16/2023 Rebuttal Expert Report of Andrew G. Iwach, M.D.	"Iwach Reb."
9/27/2023 Transcript of Deposition of Joseph Z. Izatt, Ph.D., Defendants' Expert Witness on Non-Infringement	"Izatt Tr."
8/16/2023 Rebuttal Expert Report of Joseph A. Izatt, Ph.D.	"Izatt Reb."
7/13/2023 Expert Report of John C. Jarosz, Sight Sciences' Expert Witness on Damages	"Jarosz Op."
6/13/2023 Transcript of Deposition of David Kimball, Defendants' witness designated on Sight Sciences' Rule 30(b)(6) Topics 10, 13, 16, 17, 18, and 24 (as to preclinical testing)	"Kimball Tr."
9/22/2023 Transcript of Deposition of Stephen G. Kunin, Defendants' Expert Witness on U.S. Patent Office Procedures	"Kunin Tr."
9/7/2023 Reply Expert Report of Stephen G. Kunin, in Response to the Corrected Rebuttal Expert Report of Dr. J. Crawford Downs	"Kunin Reply"

TABLE OF ABREVIATION
continued

Document/Item	Abbreviation
5/25/2023 Transcript of Deposition of Charles J. Marshall, Defendants' witness designated on Sight Sciences' Rule 30(b)(6) Topics 3 (as to domestic and marketing documents), 37, 42, 44, 45, 46, 53, 85, and 86	"Marshall Tr."
9/27/2023 Transcript of Deposition of Paul Meyer, Defendants' Expert Witness on Damages	"Meyer Tr."
8/17/2023 Expert Rebuttal Report of Paul K. Meyer	"Meyer Reb."
8/17/2023 Rebuttal Expert Report of Dr. Richard Parrish, Sight Sciences' Expert Report on Patent Validity	"Parrish Reb."
6/29/2023 Defendants' Responses to Sight Sciences' First Set of Requests for Admission (Nos. 1-39)	"RFA Responses"
8/1/2022 Second Amended Complaint, D.I. 59	"SAC"
Samuelson, et al. "Randomized Evaluation of the Trabecular Micro-Bypass Stent with Phacomulsification in Patients with Glaucoma and Cataract," AMERICAN ACADEMY OF OPHTHALMOLOGY (2011) (IVANTIS_SS_00001951)	"Samuelson" and "Samuelson2"
Samuelson, T., "The New Glaucoma Surgeries," GLAUCOMA TODAY (September/October 2004) (IVANTIS_SS_00001939-1942)	"Samuelson 2004"
6/22/2023 Transcript of Deposition of Andy Schieber, Defendants' witness designated on Sight Sciences' Rule 30(b)(6) Topics 11 (as to acceptable design-arounds) and 12 (as to known design-arounds)	"Schieber Tr."
6/29/2023 Defendants' Second Supplemental Initial Invalidity Contentions	"Second Suppl. Invalidity Contentions"
Concise Statement of Facts for Sight's Motion for Summary Judgment No. 1	"SOF1"
Concise Statement of Facts for Sight's Motion for Summary Judgment No. 2	"SOF2"
Concise Statement of Facts for Sight's Motion for Summary Judgment No. 3	"SOF3"
7/13/2023 Opening Expert Report of Angelo P. Tanna M.D., Defendants' Witness on the Invalidity of U.S. Patent Nos. 8,287,482; 9,370,443; 9,486,361; 10,314,742; and 11,389,328	"Tanna Op."
1/15/2020 Expert Report of Dr. Angelo Tanna from *Glaukos Corp. v. Ivantis, Inc.*, Case No. 8:18-cv-00620-JVS-JDE (C.D. Cal.)	"Tanna *Glaukos* Rpt."
9/26/2023 Transcript of Deposition of Angelo P. Tanna, M.D.	"Tanna Tr."

TABLE OF ABREVIATION
continued

Document/Item	Abbreviation
6/27/2023 Transcript of Deposition of Dave Van Meter, Defendants' witness designated on Rule 30(b)(6) Topics 62 and 82	"Van Meter Tr."

TABLE OF AUTHORITIES

Page(s)

Cases

TABLE OF AUTHORITIES
continued

Page(s)

TABLE OF AUTHORITIES
continued

Page(s)

TABLE OF AUTHORITIES
continued

Page(s)

Statutes

Other Authorities

I. NATURE AND STAGE OF PROCEEDINGS

Sight Sciences, Inc. ("Sight") filed this case against Ivantis, Inc. ("Ivantis") on September 16, 2021, asserting infringement of four U.S. Patents: 8,287,482 ("the '482 patent"); 9,370,443 ("the '443 patent"); 9,486,361 ("the '361 patent"); and 10,314,742 ("the '742 patent"). (*See* D.I. 1& 1-1.) On August 1, 2022, Sight filed a Second Amended Complaint asserting infringement of newly-issued U.S. Patent No. 11,389,328 ("the '328 patent"), and added Alcon Research LLC, Alcon Vision, LLC, and Alcon Inc. (collectively, "Alcon") as defendants.[1] (*See* D.I. 59 & 59-1.) Defendants filed petitions for *inter partes* review of the '482, '443, '361, and '742 patents; in March 2023, the Patent Trial and Appeal Board denied institution of all four petitions. (Exs. 49-52 (IPR2022-01529, Paper 16 (P.T.A.B. Mar. 21, 2023); IPR2022-01540, Paper 14 (P.T.A.B. Mar. 22, 2023); IPR2022-01530, IPR2022-01533, Papers 14 (P.T.A.B. Mar. 27, 2023)).)

On March 9, 2023, Magistrate Judge Fallon issued a Report and Recommendation regarding claim construction (D.I. 134), which was adopted on September 19, 2023 (D.I. 287). The parties have had ample opportunities to develop the facts in this case, deposing 43 fact and/or expert witnesses. Fact discovery closed June 29, 2023 and expert discovery closed September 28, 2023. (D.I. 93, ¶2.) A five-day jury trial is set for April 8, 2024. (D.I. 93, ¶19.)

II. SUMMARY OF ARGUMENTS

1. The Court should grant partial summary judgment of infringement as to the following claim elements, because there is no genuine dispute of material fact that the Hydrus meets them: "support," "device," and "kit"; "reducing intraocular pressure"; "fenestration"; "longitudinally insertable" and "implantable circumferentially"; "discontinuous along a perimeter of the lumen of the canal"; "introducer"; "shape memory [material / alloy]," "nickel titanium

[1] The '482, '443, '361, '742, and '328 patents are referred to collectively herein as the "Asserted Patents." Ivantis and Alcon are referred to collectively herein as "Defendants."

alloy," and "biocompatible metal"; "fluted edges"; "flexible"; "method for treating an eye condition"; "glaucoma"; "instructions on using the kit"; and "30% of C." (SOF1, ¶¶1-14.)

2. The Court should grant partial summary judgment of infringement as to the "maintain the patency" and "without substantial interference" claim elements because there is no genuine dispute of material fact that the Hydrus meets these elements. (SOF2, ¶¶1-9.)

3. The Court should grant summary judgment of no invalidity based on the iStent, the iStent Directions for Use ("DFU"), or Samuelson, because there is no genuine dispute of material fact that there was no prior public use of the iStent and neither the iStent DFU nor the Samuelson reference qualifies as a printed publication. (SOF3, ¶¶1-13.)

4. Should the Court grant Sight's Motions for Partial Summary Judgment of Infringement No. 1 and No. 2, Sight moves for summary judgment of infringement of claims 1, 5, 8, 10, and 11 of the '482 patent. (SOF1, ¶¶1-14; SOF2, ¶¶1-9.)

5. The Court should exclude the testimony of defense experts Dr. Becker, Dr. Iwach, and Mr. Meyer who opined regarding alleged non-infringing alternatives. The Court should exclude: (1) Dr. Becker's opinions regarding the availability of non-infringing alternatives because they ignore the law and are not based on sufficient facts or data; (2) Dr. Iwach's opinions regarding the availability of non-infringing alternatives because they ignore the law and are not based on sufficient facts or data, and (3) Mr. Meyer's damages opinions relating to (or depending on) the availability of non-infringing alternatives because they are based on the inadmissible opinions of Dr. Becker and Dr. Iwach, and because Mr. Meyer also ignores the law on non-infringing alternatives.

6. The Court should grant the motion to exclude Dr. Iwach's "transition zone is straight" opinion because (1) Dr. Iwach is not qualified to proffer expert opinions as to the

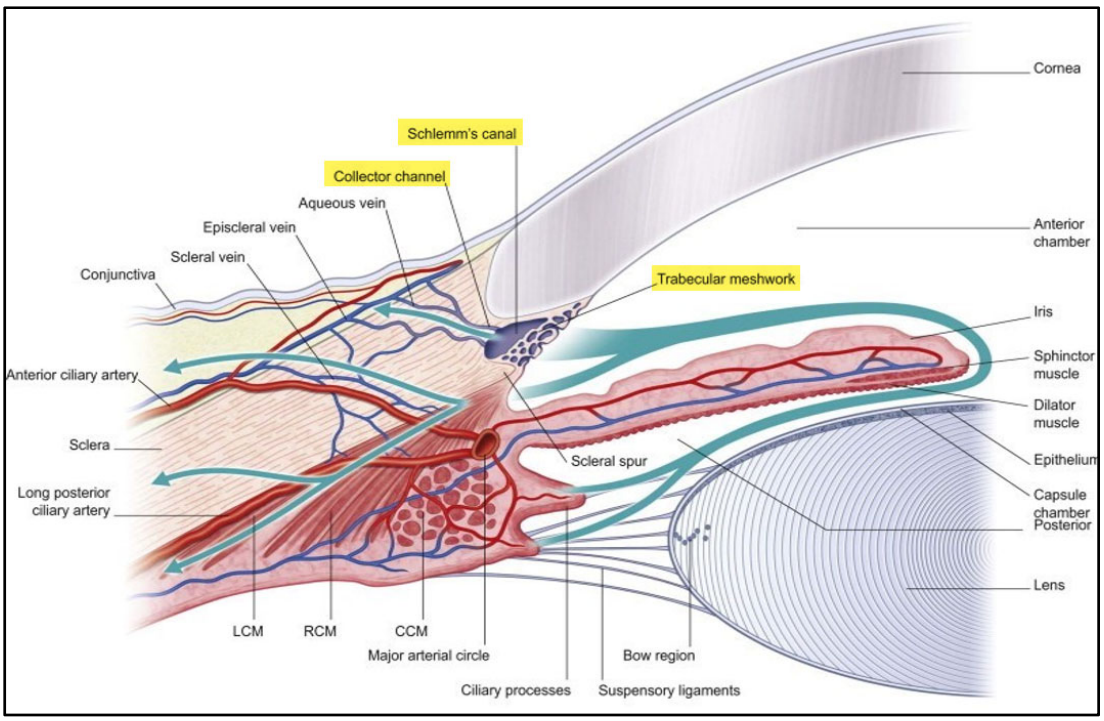
interpretation of engineering drawings, and (2) his "transition zone is straight" opinion is conclusory and based on unreliable methodology.

7. The Court should grant the motion to exclude Dr. Izatt's opinions, as well as Dr. Tanna's opinions relying thereon, regarding the "30% of C" limitation (*see infra* n.5) as to U.S. Patent 6,375,642 ("Grieshaber '642"), U.S Patent Application Publication No. 2002/00135546 ("Grieshaber '546"), iStent, and U.S. Patent Publication 2002/0165478 ("Gharib '478") because they stem from methodologies and conclusions that contradict the Court's claim construction.

8. The Court should exclude the testimony of Defendants' patent law expert, Mr. Kunin, in its entirety because: he applies an incorrect legal standard, disregarding a controlling precedential opinion by the Patent Trial and Appeal Board; his opinions do not address any factual issues in dispute and thus are unhelpful to the factfinder; and his proposed testimony includes impermissible opinions on patent law and opinions that could be misused to undermine the presumption of validity of the Asserted Patents.

III. STATEMENT OF FACTS—BACKGROUND OF THE TECHNOLOGY

Glaucoma is a potentially blinding disease characterized by increased intraocular pressure ("IOP") caused by the poor drainage of fluid from the eye. ('482, 1:24-27, 1:38-39.) In healthy eyes, a clear fluid called aqueous humor flows unobstructed through the pupil into the anterior chamber, and then exits through the eye's drainage pathway comprising the **trabecular meshwork**, **Schlemm's canal**, and **collector channels**. ('482, 1:40-52.) This diagram illustrates the natural outflow pathway; aqueous humor is denoted by teal arrows:



(Source: https://entokey.com/production-and-flow-of-aqueous-humor/)

In glaucomatous eyes, the net outflow of aqueous humor from the anterior chamber to the collector channels is reduced, thereby increasing IOP. ('482, 1:53-59, 8:31-42, Fig. 5A.) This reduction in net outflow may be caused by diseased trabecular meshwork, a narrowed or collapsed Schlemm's canal, and/or obstructed collector channels. (*Id.*; Ex. 53 (U.S. Patent No. 6,666,841), 1:27-29; Ex. 54 (IVANTIS_SS_00001298), at 55.) In 2006, treatment options for glaucoma included medications and surgeries aimed at decreasing IOP. (Ex. 55 (Parrish Reb.), ¶¶38-60.) However, these prior art treatments presented significant drawbacks. ('482, 1:60-2:51.)

The Asserted Patents improve upon the prior art treatments by disclosing and claiming minimally invasive devices that are implantable within Schlemm's canal to restore natural outflow pathways so that aqueous humor may pass from the anterior chamber through the trabecular meshwork and into collector channels, increasing flow and decreasing IOP. The Asserted Patents describe various exemplary embodiments for the claimed devices, including supports that

minimize the amount of contact between the support and the canal wall. ('482, 11:30-38.) In some embodiments, at least a portion of the support has a radius of curvature less than that of Schlemm's canal, such that a portion of the support extends out of Schlemm's canal. (*See*, *e.g.*, *id.*, Fig. 11B, 8:19-21; '443, Fig. 11D.) The Asserted Claims also recite methods of implanting the device within Schlemm's canal and a kit including an introducer for delivering the device. ('482, claim 63; '361, claim 1; '443, claim 58; '328, claim 1; '742, claim 1.)

IV. SUMMARY JUDGMENT LEGAL STANDARD

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "The burden on the moving party may be discharged by pointing out to the district court that there is an absence of evidence supporting the non-moving party's case." *Ficep Corp. v. Peddinghaus Corp.*, 587 F. Supp. 3d 115, 119 (D. Del. 2022). Conclusory statements are "insufficient" to raise a genuine dispute. *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1578 (Fed. Cir. 1989).

V. MOTION NO. 1: PARTIAL SUMMARY JUDGMENT OF INFRINGEMENT AS TO CERTAIN CLAIMED ELEMENTS OF THE ASSERTED PATENTS

A. Factual Background

The Accused Product is Defendants' Hydrus® Microstent ("Hydrus") and its accompanying Hydrus Microstent Delivery System and Instructions for Use. Hydrus is a "crescent-shaped implantable microstent pre-loaded onto a hand-held delivery system" and delivered into Schlemm's canal. (SOF No. 1, ¶3.) Hydrus is laser cut from nitinol tubing to form an arcuate (*i.e.*, curved) support with alternating "spines" for structural support and "windows" to provide outflow pathways, as depicted below (*id.*, ¶¶10-11):

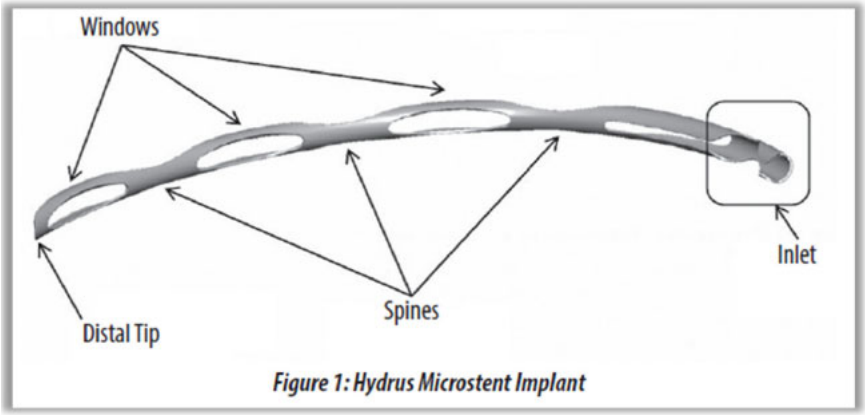


Figure 1: Hydrus Microstent Implant

(Ex. 1 at IVANTIS_SS_00041121.) Hydrus is "implanted into the eye using a hand-held delivery system (Figure 2) that provides for delivery of the implant through a stainless steel cannula into the target site in the eye." (*Id.*, ¶8.) Hydrus is indicated for use in conjunction with cataract surgery for the reduction of IOP in adult patients with mild to moderate primary open-angle glaucoma (POAG) (*id.*, ¶3).

B. Infringement Legal Standard

A patent is infringed when a person "without authority makes, uses . . . or sells any patented invention, within the United States . . . during the term of the patent." 35 U.S.C. § 271(a). "An infringement analysis involves two steps in which the court first determines the correct claim scope, and then compares the properly construed claim to the accused . . . device to determine whether all of the claim limitations are present either literally or by a substantial equivalent." *RF Del., Inc. v. Pac. Keystone Techs., Inc.*, 326 F.3d 1255, 1266 (Fed Cir. 2003).

Summary judgment of infringement is warranted where the defendant either does not dispute, or affirmatively admits, infringement. *E.g., Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1322 (Fed. Cir. 2004) (accused product infringed claim 1 as a matter of law where defendant's employees acknowledged infringement and defendants presented no expert testimony contesting infringement); *Masimo Corp. v. Philips Elecs. N. Am. Corp.*, C.A. Nos. 09-80-LPS, 11-742-LPS,

2016 WL 65427226, at *6 (D. Del. Oct. 31, 2016) (granting summary judgment of infringement when defendant's expert had "no opinion" regarding infringement of particular patent claim and defendant "has not provided evidence rebutting [plaintiff's] evidence of infringement"); *Kenexa Brassring Inc. v. Taleo Corp*., 751 F. Supp. 2d 735, 749-52 (D. Del. 2010) (granting summary judgment of infringement of the accused products where defendants did not contest that the accused products practiced the limitation and defendant's 30(b)(6) witness admitted that the products practiced the limitations).

The court may grant partial summary judgment of infringement where there is no genuine dispute that one or more elements of a claim are present in the accused product. *See, e.g., Synqor, Inc. v. Artesyn Techs., Inc.*, 709 F.3d 1365, 1379 (Fed. Cir. 2013) (affirming summary judgment of infringement as to the "isolation" claim limitation); *see also* Fed. R. Civ. P. 56(a) (where there is no genuine dispute, summary judgment is proper as to a claim or "part of" a claim).

C. Partial Summary Judgment of Infringement is Appropriate as to Certain Claimed Elements of the Asserted Patents

1. Hydrus Meets the "Support," "Device," and "Kit" Elements

Every Asserted Claim recites either a "support," "device," or "kit." *See generally* Asserted Claims. There is no dispute that the Hydrus satisfies these elements. First, Hydrus is a "support," as construed by the court. The court adopted the plain and ordinary meaning of "support" as "a structure that props something open" or "a prop." (D.I. 287 at 1.) Dr. Downs opined that the Hydrus is a support under this construction. (Ex. 18 (Downs Op.), ¶¶52-59; SOF1, ¶2.) Second, Hydrus is a "device," as consistently referred to in the Hydrus Microstent Instructions for Use ("IFU"). (SOF1, ¶3.) Third, Hydrus is provided as a "kit" because the stent is delivered preloaded into the Hydrus Microstent Delivery System and supplied with the accompanying IFU. (*Id*.)

Defendants' non-infringement expert, Dr. Andrew Iwach, offered no opinion on whether the Hydrus meets the "support," "device," or "kit" elements. (*See generally* Ex. 13 (Iwach Reb.).) As to "support," Dr. Iwach did not rebut Dr. Downs' opinion under the Court's construction. (*Id.*, ¶¶76-78.) Several of Defendants' corporate designees confirmed that the Hydrus is a device sold as part of a kit. (Ex. 4 (Marshall Tr.) 73:17-22; Ex. 8 (Hadba Tr.) 99:4-12.)

2. Hydrus Meets the "Reducing Intraocular Pressure" Element

Four of the Asserted Patents include Asserted Claims requiring "reducing intraocular pressure." ('443, claims 1, 58; '361, claim 1; '482, claim 63; '328, claim 1; *see also* '482, claims 1, 32 (reciting "[a] device"). Defendants admitted this element is met in their Answer to the SAC and responses to Sight's Requests for Admission ("RFA"). (D.I. 77, ¶42 (admitting that Hydrus is "indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure…"); Ex. 2 (RFA Responses), No. 1 (same); *see also* SOF1, ¶4.)

3. Hydrus Meets the "Fenestration" Elements

All five Asserted Patents include Asserted Claims that require the claimed support to have "at least one fenestration." ('482, claims 1, 32, 63; '443, claim 8; '361, claim 1; '742, claim 2; '328, claim 22; *see also* '328, claim 23 (reciting "a plurality of fenestrations").) Dr. Iwach, Defendants' non-infringement expert, admitted that the Hydrus has "fenestrations." (SOF1, ¶5; Ex. 7 (Iwach Tr.) 48:1-3 ("Q. But you'd know and agree that the Hydrus Microstent has windows, correct? A. It -- it has fenestrations.").

4. Hydrus Meets the "Longitudinally Insertable" and "Implantable Circumferentially" Elements

Five Asserted Claims require that the claimed support is "longitudinally insertable into a lumen of Schlemm's canal" or "implantable circumferentially within Schlemm's canal." ('482, claims 1, 32 ("longitudinally insertable into a lumen of Schlemm's canal"); '443, claims 1, 58

("implantable circumferentially within Schlemm's canal"); *see also* '328, claim 1 ("insert the support circumferentially within Schlemm's canal").) Dr. Iwach admitted that the Hydrus is inserted lengthwise (*i.e.*, longitudinally or circumferentially) within Schlemm's canal. (Ex. 7 (Iwach Tr.) 43:13-44:5 ("Q. And by the access, you mean that the length of the stent is introduced along the length of the canal? A. Correct, along the length of the canal. … Q. And do you agree that the -- when it's implanted properly in a patient, the microstent occupies a portion of the circumference of Schlemm's canal? A. Yes, it -- it occupies a portion of the entire Schlemm's canal."); *see also* SOF1, ¶6.) Defendants' corporate designee on Hydrus's design, Mr. Ahmad Hadba, admitted Hydrus is implanted circumferentially within Schlemm's canal. (Ex. 8 (Hadba Tr.) 34:18-36:24, 99:4-12, 122:6-18, 161:6-162:10.)

5. Hydrus Meets the "Discontinuous Along a Perimeter of the Lumen of the Canal" Element

The '482 patent claim 1, 63, and claims depending from these claims contain this limitation. The Court construed this element. (D.I. 287 at 2.) Dr. Downs opined that the Hydrus meets this limitation, (Ex. 18 (Downs. Op.), ¶¶112-116; SOF1, ¶7), and Dr. Iwach did not rebut Dr. Downs' opinion (*see generally*, Ex. 13 (Iwach Reb.)).

6. Hydrus Meets the "Introducer" Elements

Seven Asserted Claims recite elements requiring an "introducer" for delivering the claimed support. ('443, claims 58 ("an introducer for delivering the support"), 70 ("the support is preloaded into the introducer"), 71 ("the introducer comprises a pusher"); '742, claims 19 ("preloading the support into an introducer and delivering the support from the introducer into Schlemm's canal"), 20 ("the support is delivered from the introducer using a pusher"); '328, claim 1 (method using "an introducer comprising a cannula … wherein the support is located in a lumen of the cannula," comprising "pushing the support distally out of the distal end of the cannula to insert the support

…"); *see also* '361, claim 1 (method comprising "introducing a tubular cannula" and "inserting a support into Schlemm's canal by passing the support through the tubular cannula").

Defendants admitted that Hydrus is "**pre-loaded** onto a hand-held delivery system" and "is interlocked on a **pusher** assembly[.]" (Ex. 2 (RFA Responses), Nos. 11-13 (emphasis added); *see also* D.I. 77, ¶46.) Dr. Iwach also admitted that Hydrus is "preloaded" into a handheld "introducer" including a "pusher". (Ex. 7 (Iwach Tr.) 44:6-9 ("Q. And the Hydrus Microstent is **preloaded** into the handheld **introducer**, correct? A. Correct. The one we receive at our surgical center.") (emphasis added); *id*., 49:15-50:3 ("Q. To the best of your understanding, do you agree that the Hydrus is interlocked on a **pusher** assembly? A. I do.") (emphasis added); *see also id.*, 42:9-43:5; *see also* SOF1, ¶8.) Defendants admitted in their Answer that the Hydrus is delivered "through a stainless steel cannula" and that "'a rotatable sleeve at the distal end allows positioning and alignment of the cannula by the surgeon to direct the implant into Schlemm's canal.'" (D.I. 77, ¶46 (emphasis added).) Mr. Hadba, Defendants' corporate designee on the design of the Hydrus, confirmed that the cannula used to implant the Hydrus is "tubular" (Ex. 8 (Hadba Tr.) 105:7-11; *see also id.*, 105:24-106:3, 161:6-162:10.)

7. Hydrus Meets the "Shape Memory [Material / Alloy]," "Nickel Titanium Alloy," and "Biocompatible Metal" Elements

Eighteen Asserted Claims require that the claimed support "[is made from / comprises] a shape memory [material / alloy]," "nickel titanium alloy," or "biocompatible metal." ('443, claims 21, 23, 24, 27; '482, claims 8, 10, 11, 39, 41, 42, 77, 79, 80; '742, claims 6-9; '328, claim 25.) Defendants have repeatedly admitted that Hydrus is composed of a "shape memory [material / alloy]," a "nickel titanium alloy," and a "biocompatible metal." (SOF1, ¶9; Ex. 2 (RFA Responses), No. 3 ("Hydrus is composed of **nitinol**, a **shape memory alloy** that has been used extensively in a variety of implantable devices for its proven properties of flexibility, strength, and

biocompatibility and is a shape memory alloy.") (emphasis added).) Dr. Iwach confirmed that Hydrus is made from nitinol and "has the material properties described in the [D]efendants' response to [Sight's RFA No. 3]." (Ex. 7 (Iwach Tr.) 46:21-47:3; *see also id.*, 72:7-16.)

8. Hydrus Meets the "Fluted Edges" Element

Asserted Claims 5, 26, and 68 of the '482 patent require that the "support comprises fluted edges." ('482, claims 5, 36, 68.) The Court construed "fluted edges" to mean "edges that are uneven." (D.I. 287 at 2.) The "Hydrus has 'edges that are uneven' along its length." (Ex. 18 (Downs Op.) ¶144; SOF1, ¶11.) The alternating window/spine design of the Hydrus results in "undulations" (*i.e.*, uneven edges) along its length, as illustrated below:

(Ex. 15 (IVANTIS_SS_00000033) at 34; Ex. 14 (IVANTIS_SS_00057727) at 57732-33.)

Despite multiple opportunities to do so, Dr. Iwach refused to provide an opinion as to whether the Hydrus has fluted, or uneven, edges. (Ex. 7 (Iwach Tr.) 61:19-68:9; *see also generally* Ex. 13 (Iwach Reb.) (offering no opinion regarding "fluted edges").)

9. Hydrus Meets the "Flexible" Element

Two Asserted Claims recite that the claimed support is "flexible." ('443, claim 52; '742, claim 15.) Defendants admitted in response to Sight's RFA No. 3 that "the Hydrus is composed of nitinol, a shape memory alloy that has been used extensively in a variety of implantable devices

for its proven properties of **flexibility**, strength, and biocompatibility and is a shape memory alloy." (Ex. 2 (RFA Responses), No. 3; *see also* SOF1, ¶9.) Dr. Iwach also agreed that "the Hydrus Microstent is fabricated out of a material that's **flexible**[.]" (Ex. 7 (Iwach Tr.) 72:7-16 (emphasis added); *see also id.*, 46:21-47:6.)

10. Hydrus Meets the "Instructions on Using the Kit" Element

Asserted Claim 59 of the '443 patent requires that the claimed kit "further compris[es] instructions on using the kit." ('443, claim 59.) Defendants admitted in response to Sight's RFA No. 20 that the "Hydrus is sold to physicians with instructions for use." (Ex. 2 (RFA Responses), No. 20; SOF1, ¶3.) Dr. Iwach agreed that the Hydrus includes instructions for use. (Ex. 7 (Iwach Tr.) 55:6-9.)

11. Hydrus Meets the "30% of C" Element

Asserted Claims across four of the Asserted Patents require that "when the support is disposed within a cylindrical section of the lumen of the canal having an internal wall surface area C, the support contacts less than 30% of C." ('482, claims 1, 5, 7, 8, 10, 11, 15, 18, 21, 23, 32, 36, 38, 39, 41, 42, 46, 49, 52, 54, 63, 68, 69, 70, 73, 77, 79, 80; '443, claims 1, 8, 11, 12, 21, 23, 24, 27, 42, 43, 46, 52, 54, 55, 56, 57, 58, 59, 70, 71; '742, claim 13; '328, claim 21.)[2] The Court construed this term to mean that, "when the support is disposed within a section of Schlemm's canal, the internal wall surface area C of that section is estimated by viewing the inside of Schlemm's canal as a slightly arcuate cylinder having length L, extending circumferentially from a first end X_1 to a second end X_2 of the support, and inside radius R_i, and the support contacts less than 30% of [the surface area of] C." (D.I. 287 at 1.)

[2] For ease of reference, this brief refers to this element as the "30% of C" element.

Dr. Downs provided a detailed analysis of the Hydrus structure and concluded that Hydrus only makes "point contact" with the arcuate (*i.e.*, curved) cylinder representing Schlemm's canal. (Ex. 18 (Downs Op.), ¶¶121, 140.) He ultimately concluded that the contact area between the Hydrus and the best-fit hypothetical cylinder was "**less than 1%**." (*Id.*, ¶140; *id.* at Table 3, ¶¶141-143; SOF1, ¶12.) Therefore, the Hydrus satisfies the "30% of C" element. (*Id.*)

Dr. Downs' opinions are unrebutted. Defendants' expert reports are devoid of any noninfringement position on this claim element. (*See generally* Ex. 13 (Iwach Reb.); SOF1, ¶12.) At deposition, Dr. Iwach confirmed that he does not have an opinion regarding whether the Hydrus meets the "30% of C" element:

> Q. Do you have an opinion sitting here today whether the Hydrus Microstent meets the less than "30 percent of C" limitation of the patents-in-suit?
>
> A. This is a nuanced question that I would need to take some time. I don't want to speculate here today. So I want to take some time for careful consideration and analysis, to -- to formulate an opinion.
>
> Q. And you haven't done that yet? . . .
>
> THE WITNESS: I have -- well, to answer to that particular question, I would need to do an analysis and study to come to a conclusion to come to an answer to your question.

(Ex. 7 (Iwach Tr.) 196:4-197:2.) Dr. Iwach's Rebuttal Report's analysis regarding the "30% of C" element is limited to a critique of an Ivantis engineering report that Dr. Downs does not rely on to establish that the Hydrus infringes the "30% of C" element. (Ex. 18 (Downs Op.) ¶¶117-140, 142-143.) Dr. Downs merely cites this report to show that Ivantis uses point contact analysis to estimate the amount of contact between the Hydrus and a cylindrical surface. (Ex. 13 (Iwach Reb.) ¶¶120-121; *cf.* Ex. 18 (Downs Op.) ¶141 (citing Ex. 82 (IVANTIS_SS_00293425)); *see also* Ex. 57 (Downs Reply), ¶8 & n.1; *see also id.* ¶65.) Thus Dr. Iwach's critique of the engineering report does not create a genuine dispute.

VI. MOTION NO. 2: PARTIAL SUMMARY JUDGMENT OF INFRINGEMENT AS TO THE "MAINTAIN THE PATENCY" AND "WITHOUT SUBSTANTIAL INTERFERENCE" ELEMENTS

Sight incorporates by reference Sections V.A and V.B set forth above regarding the Factual Background and Infringement Legal Standard, respectively. There is no genuine dispute of material fact that the Hydrus satisfies the below claim elements, thus partial summary judgment of infringement is warranted as to these elements. *E.g.*, *Toro Co.*, 355 F.3d at 1322.

1. The Hydrus Meets the "Maintain the Patency" Element of the Asserted Claims

Several of the Asserted Claims in the '482 and '443 Patents require that a support "maintain patency of at least a portion [of the canal]" or "maintain the patency of at least a portion [of the canal]." ('482, claims 1, 18, 32, 49, 63, 73; '443, claims 1, 58.) Although not construed by the Court, the patents expressly define the term "maintain patency of at least a portion of" Schlemm's canal to mean "the support operates to keep the canal at least partially unobstructed to transmural flow, such that fluid can 1) exit through the trabecular meshwork; 2) traverse the canal; and 3) drain via the collector channels." ('482, 7:28-33.)

Defendants' expert Dr. Iwach has not opined that Hydrus obstructs flow through the trabecular meshwork or into the collector channels. Ultimately, Dr. Iwach opines that "it is unlikely that much, if any, aqueous humor flows across the trabecular meshwork into Schlemm's canal after Hydrus is implanted…" (Ex. 13 (Iwach Reb.) ¶109.) But Dr. Iwach has not provided any evidence, including, for example, fluid dynamics calculations or modeling, to show that there would be no aqueous outflow through the trabecular meshwork once Hydrus was implanted. (*See id.*) Dr. Iwach's conclusory opinion cannot overcome [redacted]

[redacted]

Dr. Downs marshaled the abundant evidence and opined that this element is satisfied. (Ex. 18 (Downs Op.) ¶¶86-92, 95-111; and Ex. 57 (Downs Reply) ¶¶44-64.) In summary:

- Hydrus [redacted] Ex. 20 (IVANTIS_SS_00128553) at 128564).)
- Defendants have repeatedly advertised to surgeons and patients [redacted] (*See* Ex. 22 (IVANTIS_SS_00006997) at 7001; *see also* SOF2, ¶4 ([redacted] Ex. 21 (IVANTIS_SS_00415663) at 415712).)
- Defendants have [redacted] (*See* SOF2, ¶6; Ex. 26 (IVANTIS_SS_00010785) at 10790 ([redacted]));
- Ivantis [redacted] (SOF2, ¶5; Ex. 24 (IVANTIS_SS_00074707) at 74723 [redacted]

[redacted]); *see also* Ex. 25 (IVANTIS_SS_00023750) at 23768 [redacted].)

- Defendants' witnesses [redacted]. David Kimball, former Alcon Fellow and Director of Manufacturing at Ivantis, testified that [redacted] (Ex. 9 (Kimball Tr.) at 94:21-23.); *id.*, 95:10-14 [redacted]); Ex. 8 (Hadba Tr.) 119:3-12 ([redacted]); Ex. 27 (Schieber Tr.) 51:19-52:3 ([redacted]); Ex. 28 (Van Meter Tr.) 38:8-12; 38:21-24; 171:2-12 [redacted].)
- Defendants' expert Dr. Tanna [redacted]. (SOF2, ¶9.)

Defendants' failure to provide any evidence rebutting the mountain of evidence above warrants partial summary judgment as to this element.

2. Hydrus Meets the "Without Substantial Interference" Elements

Many of the Asserted Claims require that "fluid may traverse the canal without substantial interference from the support" or "support does not substantially interfere with the

[longitudinal/transmural] flow" or "does not significantly block fluid outflow," collectively referred to as the "without substantial interference" terms. ('482, claims 1, 32; '443, claims 1, 56, 57, 58; '361, claims 6, 7, 8; '742, claims 17, 18; '328, claims 7, 8.) The Court construed all of these terms to mean, "the support does not significantly block either fluid outflow from the trabecular meshwork or fluid outflow to the collector channels." (D.I. 287 at 1.) This term is thus related to the "maintains patency" term, specifically requiring that fluid outflow from the trabecular meshwork into Schlemm's canal may not be significantly blocked by the support.

Dr. Iwach has not opined that Hydrus substantially interferes with flow and has not created a genuine dispute of fact about this claim element. The evidence above related to the "maintains patency" term overwhelmingly [redacted] (SOF2, ¶¶3-9.) While Dr. Iwach declines to acknowledge [redacted], he does not provide any opinion that Hydrus does, in fact, substantially interfere with fluid outflow. To the contrary, Dr. Iwach acknowledges that there may be some amount of flow through the trabecular meshwork. (Ex. 13 (Iwach Reb.) ¶114.) Dr. Iwach's position that "it is unlikely that **much**, if any, aqueous humor flows across the trabecular meshwork" into Schlemm's canal after Hydrus is implanted. (Ex. 13 (Iwach Reb.) ¶114 (emphasis added)), absent any evidentiary support, is insufficient to raise a genuine dispute of fact in view of the overwhelming evidence of flow, summarized above.

VII. MOTION NO. 3: SUMMARY JUDGMENT OF NO INVALIDITY BASED ON ISTENT, THE ISTENT DFU, OR SAMUELSON

A. Factual Background

Glaukos Corporation manufactures an intraocular device called iStent, which is a trabecular bypass shunt used for the treatment of open angle glaucoma. (Ex. 40 (iStent DFU) SGHT0053791.) Defendants rely on iStent as a primary reference in arguing that the Asserted Claims are invalid based on anticipation and/or obviousness. (Ex. 58 (Second Suppl. Initial Invalidity Contentions), at 8; *see also* Ex. 41 (Tanna Op.) at pp. 53, 242-288, 359-363, 491-503, 525-530, and 562-569.)

The iStent was not approved by the FDA until June 2012. (SOF3, ¶6; Ex. 43 (iStent Pre-Marketing Approval letter from the FDA, dated June 25, 2012) (SGHT0170452-57).) Defendants' Invalidity expert, Dr. Tanna, admitted (1) there were no public uses of the iStent in the United States before June 26, 2006 (SOF3, ¶9); (2) availability for clinical trials does not equate to public availability (SOF3, ¶10; Ex. 44 (Tanna Tr.) 258:13-18 ("Q. Is availability for clinical trials public availability according to your definition? … A: I -- I don't think so, no."); and (3) he had no evidence the iStent Directions for Use ("DFU") were available before June 26, 2006. (SOF3, ¶11; Ex. 44 (Tanna Tr.) 229:8-14 ("Q. These directions for use, do you have any evidence to support the proposition that these directions for use were available prior to June 26, 2006? … A: No, I don't personally know that it was.").) Defendants have failed to establish that iStent is prior art under the relevant pre-AIA standards.

B. Prior Art Legal Standard

Under Section 102 of the pre-AIA legal framework, "a person shall be entitled to a patent unless—(a) the invention was **known or used by others in this country**, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or (b) the invention was patented or described in a printed publication in this or a foreign country or **in public use or on sale in this country**, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102 (2002) (emphasis added). For a

device to qualify as prior art, knowledge or use of the device must be publicly accessible; "secret or confidential third-party uses do not invalidate later-filed patents." *Sunoco v. Powder Springs Logistics*, C.A. No. 17-1390-LPS-CJB, 2020 WL 9438750, at *2 (D. Del. Feb. 20, 2020) (quoting *Dey, L.P. v. Sunovion Pharms., Inc.*, 715 F.3d 1351, 1355 (Fed. Cir. 2013)); *Delano Farms Co. v. Cal. Table Grape Comm'n*, 778 F.3d 1243, 1247 (Fed. Cir. 2015) (same). Defendants must prove that a reference is prior art by clear and convincing evidence. *ATEN Int'l Co., Ltd. v. Uniclass Tech. Co., Ltd.*, 932 F.3d 1364, 1368 (Fed. Cir. 2019) (citing *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1578 (Fed. Cir. 1996).

C. Summary Judgment of No Anticipation or Obviousness of the Asserted Claims Is Appropriate Because the iStent Device Does Not Qualify as Prior Art

1. Whether iStent is prior art turns on whether iStent was "in public use" or "publicly accessible" in this country before June 26, 2006

Sight is entitled to summary judgment of no prior art invalidity based on the iStent device because Defendants have not met their burden of proving iStent is prior art. It is undisputed that iStent is a device, and therefore is not a patent or printed publication under 35 U.S.C. § 102. Thus, to qualify iStent as prior art, Defendants must establish by clear and convincing evidence that it was either "known or used by others," in the U.S. (§ 102(a)) or "in public use or on sale" in the U.S. (§ 102(b)). Dr. Tanna, concedes that iStent was not on sale in the U.S. prior to June 26, 2006. (SOF3, ¶8.) Thus, whether iStent is prior art rests solely on if it was "in public use" or "publicly accessible" in the U.S. prior to June 26, 2006. It was not.

2. Dr. Tanna admits that there were no public uses of the iStent in the U.S. before June 26, 2006

It is undisputed that there were no public uses of iStent prior to June 26, 2006. Defendants' expert on invalidity, Dr. Tanna admitted the same: "Q. And was the iStent available publicly – were there public prior uses before 2006, June 2006, in the United States? A. Define "public prior

use." Q: Public prior use is a use that's open to the public and is not an experimental use. A: In the United States, no, there was not public prior use by 2006." (Ex. 44 (Tanna Tr.) 226:21-227:8 (objections omitted).) Dr. Tanna's frank admission confirms that the clinical trials for iStent in the United States did not constitute public uses. Moreover, Dr. Tanna was asked about his own ability to access iStent in 2006: "Q. You didn't actually have access he[sic] to an iStent in 2006, correct? A. Well, I had access to the iStent in that I could look at pictures of the iStent. I could look at papers and publications about the iStent." (*Id.*, 80:14-19.) Dr. Tanna's response confirms that the iStent device itself was not available to Dr. Tanna, and by reason, not to the public. To the extent that Defendants can identify authentic prior art pictures, papers, and publications about the iStent, they are entitled to rely on the disclosures in those documents as prior art **publications**. However, Defendants have failed to identify any reference that suggests that the iStent **device** was publicly available.

3. Neither Bahler Nor Samuelson Establishes the Public Availability of the iStent Device prior to June 26, 2006

Defendants cannot establish the public availability of the iStent device through either of the two references they rely upon for this purpose. Neither Bahler nor Samuelson prove that the iStent device was publicly available. (Ex. 37 (Exhibit 443-A13 to Initial Invalidity Contentions) at 1.) Bahler was published in 2004 and describes a cadaveric eye study using the iStent. (Ex. 60 (Bahler).) While Defendants may seek to rely on Bahler as a prior art publication under §102(b), there is no genuine dispute that Bahler does not establish that iStent was made available to others without any expectation of confidentiality or restrictions on use. *See Dey, L.P. v. Sunovion Pharms., Inc*., 715 F.3d 1351, 1355 (Fed. Cir. 2013) ("[E]ven in the case of third-party uses, being 'accessible to the public' still requires public availability; secret or confidential third-party uses do not invalidate later-filed patents."); *see also Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471

F.3d 1369, 1380 (Fed. Cir. 2006) ("Public use includes 'any [public] use of [the claimed] invention by a person other than the inventor who is under no limitation, restriction or obligation of secrecy to the inventor.'" (quoting *In re Smith*, 714 F.2d 1127, 1134 (Fed.Cir.1983))). Bahler indicates it was "[s]upported in part by Glaukos Corporation" and one of the co-authors had been affiliated with Glaukos ("Dr. Gregory T. Smedley is no longer with Glaukos Corporation." (Ex. 60 (Bahler) at 988.) A publication co-authored by a Glaukos employee does not prove the iStent was available to the public. *See Delano Farms Co.*, 778 F.3d at 1247 ("The adequacy of any confidentiality guarantees are measured in relation 'to the party in control of the allegedly invalidating prior use.'" (internal citations omitted)).

Samuelson is another publication that resulted from a collaboration with Glaukos that fails to establish public availability of the iStent. Samuelson was published in 2011 and describes results from an iStent clinical trial. (Ex. 39 (Samuelson) at 462.) This article indicates on its face that it is "for the US iStent Study Group." (Ex. 39 (Samuelson) at 459.) The Footnotes and Financial Disclosures indicate that one of the co-authors is from Glaukos Corporation (*id.* at 467 n.3) and that Glaukos funded the study. (*Id.*) To the extent Samuelson describes clinical trials that were ongoing prior to June, Dr. Tanna admits those clinical trial uses of iStent were not public uses. (SOF3, ¶10; Ex. 44 (Tanna Tr.) at 258:13-18 (Q: Is availability for clinical trials public availability according to your definition? A: I -- don't think so, no.").) Dr. Tanna's testimony is consistent with Dr. Downs' testimony that in clinical trials, "there's often nondisclosure agreements involved, if not in every one I've ever been involved with." (Ex. 61 (Downs Tr.) 63:20-23.)

4. The iStent Directions for Use Do Not Establish That the iStent Was "In Public Use" or "Publicly Accessible" Before June 26, 2006

The iStent Directions for Use ("DFU") also do not establish that the iStent device was "in public use" or "publicly accessible" in this country before June 26, 2006. Importantly, the iStent DFU does not qualify as a printed publication. Defendants have failed to provide clear and convincing evidence that it was publicly available before June 26, 2006. iStent did not receive pre-marketing approval from the FDA until June 25, 2012. (SOF3, ¶6; Ex. 43 (iStent Pre-Marketing Approval letter from the FDA, dated June 25, 2012) (SGHT0170452-57).) Defendants failed to adduce any evidence that the iStent DFU would have been disseminated or otherwise made available to interested POSAs exercising reasonable diligence. *See Bruckelmyer v. Ground Heaters, Inc.*, 445 F.3d 1374, 1378 (Fed. Cir. 2006) (citing *In re Wyer*, 655 F.2d 221, 226 (C.C.P.A. 1981)) (public accessibility requires showing the document has been disseminated such that persons interested and ordinarily skilled in the subject matter can locate it, among other things). At most, Dr. Tanna testified that the iStent DFU, or a version of the instructions for iStent, may have been available to physicians participating in the iStent clinical trials. (Ex. 44 (Tanna Tr.) 257:18-25.) On re-direct, Dr. Tanna confirmed that "availability for clinical trials" was not the same as public availability. (*Id.* at 258:13-18.) Because the DFU itself was not publicly available before the priority date of the Asserted Patents, it cannot demonstrate public availability of the iStent.

In addition, the iStent DFU does not establish that the iStent was made available to others without any expectation of confidentiality or restrictions on use before June 2006. *See Eli Lilly*, 471 F.3d at 1380. While the DFU references iStent clinical trials occurring as early as April 2005, it provides no evidence about the public accessibility of the iStent, or what was known about the device without confidentiality obligations or restrictions on use prior to June 2006.

Based on the record evidence, Defendants cannot meet their burden of demonstrating by clear and convincing evidence that the iStent device was publicly available prior art.

VIII. MOTION NO. 4: CONDITIONAL MOTION FOR SUMMARY JUDGMENT OF INFRINGEMENT OF CLAIMS 1, 5, 8, 10, AND 11 OF THE '482 PATENT

If the Court grants Sight's Motions No. 1 and No. 2 for Partial Summary Judgment of Infringement, summary judgment of infringement is appropriate for claims 1, 5, 8, 10 and 11 of the '482 patent. (*See* '482, col. 18.) Claim 1 is provided in the chart below with the terms identified that correspond to Motions No. 1 and No. 2.

1. A **device** comprising:	MSJ No. 1; SOF1, ¶3
a **support**	MSJ No. 1; SOF1, ¶2
having at least one **fenestration**	MSJ No. 1; SOF1, ¶5
that is **longitudinally insertable** into a lumen of Schlemm's canal	MSJ No. 1; SOF1, ¶6
the support having a cross-sectional dimension sufficient to at least partially prop open Schlemm's canal upon insertion into the canal, and	SOF2, ¶¶2, 3; *see also* Ex. 13 (Iwach Reb.), ¶264.
to thereby **maintain patency** of at least a portion of the canal	MSJ No. 2; SOF2, ¶¶3-6, 9
so that fluid may traverse the canal **without substantial interference** from the support	MSJ No. 2; SOF2, ¶¶3-6, 9
wherein when the support is disposed within a lumen of Schlemm's canal, contact between the support and the wall of the canal is **discontinuous along a perimeter of the lumen of the canal**	MSJ No. 1; SOF1, ¶7
and wherein when the support is disposed within a cylindrical section of the lumen of the canal having an internal wall surface area C, **the support contacts less than 30% of C**.	MSJ No. 1; SOF1, ¶12

In addition to the support in SOF2, ¶¶2, 3 for the term "**the support having a cross-sectional dimension sufficient to at least partially prop open Schlemm's canal** upon insertion

into the canal," Dr. Iwach confirms that this term is satisfied in his discussion of an alleged non-infringing alternative design. Dr. Iwach states: "[the alleged non-infringing alternative] device therefore **dilates the canal in exactly the same way** as the commercialized Hydrus® Microstent (due to the outer cross-sectional dimensions), the opening that the stent provides for aqueous flow longitudinally through the canal is identical (due to the inner cross-sectional dimensions), and the stent provides the same amount of access to the collector channels on the outer wall of Schlemm's canal . . ." (Ex. 13 (Iwach Reb.), ¶ 264.)

Claims 5, 8, and 10 each depend from claim 1 and additionally recite fluted edges, a biocompatible metal, and a shape memory material, respectively. Claim 11 depends from claim 10 and additionally recite a nickel titanium alloy. As discussed in Motion No. 1, Hydrus meets these terms:

5. The device of claim 1, wherein the support comprises **fluted edges**.	MSJ No. 1; SOF1, ¶11
8. The device of claim 1, wherein the support comprises a **biocompatible material**.	MSJ No. 1; SOF1, ¶9
10. The device of claim 1, wherein the support comprises a **shape memory material.**	MSJ No. 1; SOF1, ¶9
11. The device of claim 10, wherein the support comprises a **nickel titanium alloy**.	MSJ No. 1; SOF1, ¶9, 10

Thus, if Motions No. 1 and No. 2 are granted, summary judgment of infringement of claims 1, 5, 8, 10, and 11 should be granted.

IX. FRE 702 AND *DAUBERT* STANDARDS

Rule 702 allows for opinion testimony from a qualified expert if the following requirements are each met: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based

on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case. Fed. R. Evid. 702. The party offering the testimony has the burden to prove admissibility. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592 n.10 (1993). The court functions as a "gatekeeper" to determine whether a party's proffered expert testimony is "not only relevant, but reliable" (*id.* at 589) and to "assur[e] that irrelevant evidence does not unfairly prejudice the trial." *Magnivision, Inc. v. Bonneau Co.*, 115 F.3d 956, 961 (Fed. Cir. 1997) ("The obligation of the trial judge to act as 'gatekeeper' is founded on the potential for prejudice."). *See also Seaboard Lumber Co. v. United States*, 308 F.3d 1283, 1301–02 (Fed. Cir. 2002) ("In *Daubert,* the Supreme Court reaffirmed that the trial judge is to screen scientific evidence for relevance and reliability. ... [W]ithout this screening function, the jury might be exposed to confusing and unreliable expert testimony. … [I]n assessing scientific testimony, the judge should also be mindful of, inter alia, Fed. R. Evid. 403 (permitting the exclusion of relevant evidence 'if its probative value is substantially outweighed by the danger of ... misleading the jury').")

X. MOTION TO EXCLUDE DR. IWACH'S "TRANSITION ZONE IS STRAIGHT" OPINION

A. Factual Background

The "transition zone" of the Hydrus refers to the section of the microstent between the portion of the device intended to lie within Schlemm's Canal and the portion intended to extend into anterior chamber. (Ex. 21 (IVANTIS_SS_00415663) at 415693.) Dr. Iwach opines that the "the entire transition zone is straight and has no . . . curvature" (the "transition zone is straight" opinion). (Ex. 13 (Iwach Reb.) ¶140.) This "transition zone is straight" opinion is the sole basis for his opinion that the Hydrus is not a support that comprises an "arcuate member" as claimed by the Asserted Patents. (*Id.*, ¶141.) Dr. Iwach's opinion is based on his visual inspection of a single

Hydrus engineering drawing, reproduced below, that he contends shows a straight transition zone in the boxed region he magnified and annotated. (*Id.*)

(Ex. 13 (Iwach Reb.) ¶ 140.)

B. Dr. Iwach Is Not An Engineer And Used Unreliable Methodology

Dr. Iwach's opinion that the Hydrus transition zone is straight hinges entirely on a conclusory interpretation of the Hydrus engineering drawing shown above, and that opinion is contradicted by the testimony of Defendants' corporate designees and Defendants' design and product management documents. *Magnetar Techs. Corp. v. Six Flags Theme Parks Inc.*, C.A. No. 07-127-LPS-MPT, 2014 WL 529983, at *4 (D. Del. Feb. 7, 2014) ("[A] court may exclude an expert's testimony or opinion if it is conclusory, lacks analysis, or the chasm between the analysis and opinion cannot be bridged."). Dr. Iwach does not have an engineering degree (Ex. 7 (Iwach Tr.) 11:8-12:3; Ex. 13 (Iwach Reb.) ¶¶4-12), and his opinion is not based on the "methods and procedures of science[,]" but instead based on "subjective belief" and "unsupported speculation[.]" *Daubert*, 509 U.S. at 590.

1. Dr. Iwach Lacks Qualifications to Proffer Expert Opinions as to the Interpretation of Engineering Drawings

As further explained in Section X.C below, Dr. Iwach's "transition zone is straight" opinion is based solely on his conclusion that the Hydrus engineering drawing, shown above, depicts a straight transition zone. Under *Daubert* and Fed. R. Evid. 702, the Court considers "a trilogy of restrictions on expert testimony: qualification, reliability and fit." *Cirba Inc. v. VMware, Inc.*, C.A. No. 19-742- GBW, 2023 WL 3151853, at *1 (D. Del. Apr. 18, 2023) (quoting *Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 404-05 (3d Cir. 2003)). While Dr. Iwach may be a qualified ophthalmologist, he is not an engineer. (Ex. 7 (Iwach Tr.) 9:22-25 and 11:8-12:3; Ex. 13 (Iwach Reb.) ¶¶4-12.) Dr. Iwach agreed, in fact, that he was not offering himself or his opinions "as an expert in engineering in this case." (Ex. 7 (Iwach Tr.) 17:7-10.) Thus, he lacks the qualifications to provide expert opinions predicated on engineering principles. *See Advanced Med. Optics, Inc. v. Alcon, Inc.*, No. CIV.A. 03-1095-KAJ, 2005 WL 782809, at *9 (D. Del. Apr. 7, 2005) (excluding opinion of expert, an eye surgeon, where opinion was predicated on engineering knowledge, which was beyond the surgeon's area of expertise).

2. Dr. Iwach's "Transition Zone Is Straight" Opinion Is Conclusory and Incompatible with Record Evidence

Dr. Iwach's opinion that the inlet portion of the Hydrus lacks curvature is *ipse dixit* and should be excluded. "Opinion testimony that is not 'helpful' is not admissible, and, in particular, testimony consisting of 'conclusory assertions' and 'bald conclusion[s]'—as in 'an expert's testimony that "it is so"'—does not assist the factfinder in understanding the evidence or determining facts in issue." *Genuine Enabling Tech. LLC v. Sony Corp.*, No. 17-cv-135, 2022 WL 17325656, at *6–8 (D. Del. Nov. 28, 2022) (citations omitted), *denying reconsideration*, 2023 WL 4686024, at *5–8 (D. Del. July 20, 2023); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137,

157 (1999) (courts are not required to admit opinion "evidence that is connected to existing data only by the *ipse dixit* of the expert." (citation omitted)).

Dr. Iwach's opinion is not supported by sufficient facts. An "expert must have 'good grounds' for his [or] her belief," yet Dr. Iwach fails to identify any corroborating evidence for his "transition zone is straight" opinion. *Schneider*, 320 F.3d at 404 (citations omitted). He spoke with no one at Alcon or Ivantis regarding his opinion, he did not review Hydrus documentation (other than looking at the drawing above) (Ex. 7 (Iwach Tr.) 198:5-12, 201:11-15); nor did he examine a finished Hydrus Microstent. (*Id.*, 198:20-24.) Dr. Iwach's opinion rests solely on his feeling that [redacted]. (*Id.*, 197:10-198:4 [redacted]

"Feeling" is not enough. *Genuine Enabling*, 2022 WL 17325656, at *6 ("[A]n expert's opinions are not admissible merely because the expert says, in effect, 'trust me, I know.'" (quoting *Mooring Cap. Fund, LLC v. Phoenix Cent., Inc.*, No. 06-cv-6, 2009 WL 4263359, at *5 (W.D. Okla. Feb. 12, 2009))). This type of conjecture is precisely the kind of "because I say so" opinion that must be excluded. *Daubert*, 509 U.S. at 590; *Kumho Tire*, 526 U.S. at 157; *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997); Fed. R. Evid. 702. Dr. Iwach's feeling also contradicts the drawing's stated dimensions, **which he could not interpret**. [redacted] (Ex. 7 (Iwach Tr.) 200:17-201:3.) Dr. Iwach could not answer [redacted] (*Id.*, 201:1-203:6.)

Dr. Iwach also failed to account for undisputed manufacturing steps, including [redacted] David Kimball, former Alcon Fellow and Director of Manufacturing at Ivantis and Defendants' corporate designee as to the design and development of the Hydrus, [redacted] t. (Ex. 9 (Kimball Tr.) 84:18-85:24, 86:23-87:1, 87:25-88:10.) Todd Abraham, Vice President of Operations for Ivantis, further explained: [redacted] (Ex. 62 (Abraham *Glaukos* Tr.) 277:14-20.) Dr. Iwach [redacted] (Ex. 7 (Iwach Tr.) 201:5-10.) That oversight is fatal to his analysis.

Moreover, Dr. Iwach's *ipse dixit* as to the curvature (or lack thereof) of the Hydrus transition zone is incompatible with admissions by Defendants' witnesses. *See Gen. Elec.*, 522 U.S. at 146 (district court need not admit opinion evidence "that is connected to existing data only by the *ipse dixit* of the expert."). For example, Mr. Kimball explained that the Hydrus [redacted] (Ex. 9 (Kimball Tr.) 122:6-123:15, 80:8-16.)[3] Dr. Ahmad Hadba, Alcon's Director of Glaucoma Device Research Development and Defendants' corporate designee as to Defendant's documentation of research, development, and commercial designs of

[3] *See also* Ex. 9 (Kimball Tr.) 84:18-85:24 ([redacted], 86:23-87:1, 87:25-88:10 [redacted]), 89:21-90:24, 202:6-15.

the Hydrus, [redacted]

(Ex. 8 (Hadba Tr.) 134:5-20 (emphasis added).[4])

Lacking reliable methodology for his "transition zone is straight" opinion, Dr. Iwach is merely offers subjective beliefs and "feelings" that must be excluded. *Daubert*, 509 U.S. at 590. *See Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993) (unsupported opinion contradicted by indisputable record facts cannot support a jury verdict).

XI. MOTION TO PARTIALLY EXCLUDE DR. IZATT'S OPINION AS TO THE 30% OF C LIMITATION AND DR. TANNA'S OPINIONS RELYING THEREON

Dr. Izatt's opinions, as well as Dr. Tanna's opinions relying thereon, regarding the "30% of C" limitation[5] as to U.S. Patent 6,375,642 ("Grieshaber '642"), U.S Patent Application Publication No. 2002/00135546 ("Grieshaber '546"), iStent; and U.S. Patent Publication 2002/0165478 ("Gharib '478") should be excluded because they use methodologies and

[4] *See also* Ex. 8 (Hadba Tr.) 132:17-22, 140:12-24, 141:23-142:1.
[5] The "30% of C" limitation as used here refers to the claim limitation "wherein when the support is [disposed/inserted] within a cylindrical section of the lumen of the canal having an internal wall surface area C, the support contacts less than 30% of [the surface area of] C."

conclusions that contradict the Court's claim construction. *Minerva Surgical, Inc. v. Hologic, Inc.*, C.A. No. CV 18-00217-JFB-SRF, 2021 WL 3048447, at *9 (D. Del. July 20, 2021) (excluding expert testimony where expert's methodology and conclusions failed to conform to the court's claim construction); *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1321 (Fed. Cir. 2009) ("Once a district court has construed the relevant claim terms . . . that legal determination governs for purposes of trial. No party may contradict the court's construction to a jury.").

The Court defined the "30% of C" limitation as "wherein when the support is disposed within a section of Schlemm's canal, the internal wall surface area C of that section is estimated by viewing the inside of Schlemm's canal as **a slightly arcuate cylinder** . . . [wherein] the support contacts less than 30% of C." (D.I. 287 at 1 (emphasis added).) Dr. Izatt's application of the "30% of C" limitation ignores the Court's construction. In his Opening Report, Dr. Izatt relies on a non-arcuate cylinder to determine whether the "30% of C" limitation is met by Grieshaber '642, Grieshaber '546, iStent, and Gharib '478. (Ex. 64 (Izatt Op.) ¶¶65-69, 75-77, 104-106, 137-139, 142-144, 148-150.) At deposition he admitted that his modeling for the "30% of C" limitation as to these references used a straight (i.e., non-arcuate) cylinder. (Ex. 65 (Izatt Tr.) at 40:16-41:2, 42:5-17, 43:14-44:4, 58:12-59:3, 59:25-60:12.) Dr. Tanna relies on Dr. Izatt's conclusions that improperly use a straight cylinder. (Ex. 41 (Tanna Op.) ¶¶164-165, 168, 170-171, 173-174, 175-177, 448, 450-452, 670-672, 728-729.)

Dr. Izatt's misapplication of the Court's construction regarding the "30% of C" limitation as to Grieshaber '642, Grieshaber '546, iStent, and Gharib '478 renders his corresponding conclusions unreliable and inadmissible. Accordingly, these opinions, as well as those of Dr. Tanna relying thereon, should be excluded. *Integra Lifesciences Corp. v. HyperBranch Med. Tech., Inc.*, C.A. No. 15-819-LPS-CJB, 2018 WL 1785033, at *5 (D. Del. Apr. 4, 2018) (excluding

expert testimony inconsistent with the Court's claim construction); *Liquid Dynamics Corp. v. Vaughan Co.*, 449 F.3d 1209, 1224 n.2 (Fed. Cir. 2006) (same).

XII. MOTION TO EXCLUDE OPINIONS ON NON-INFRINGING ALTERNATIVES

Defendants rely on allegedly non-infringing alternatives (NIAs) for their damages defenses. Defendants proffer three experts regarding the alleged NIAs, FDA regulatory expert Dr. Karen Becker, technical expert Dr. Andrew Iwach, and damages expert Paul Meyer. The Court should exclude: (1) Dr. Becker's opinions in their entirety because they ignore the law and are not based on sufficient facts or data; (2) Dr. Iwach's opinions regarding the availability of non-infringing alternatives because they ignore the law and are not based on sufficient facts or data, and (3) Mr. Meyer's damages opinions relating to (or depending on) the availability of non-infringing alternatives because they are based on the inadmissible opinions of Dr. Becker and Dr. Iwach, and because Mr. Meyer also ignores the law.

A. Becker and Iwach's Opinions Are Unreliable Because They Failed to Consider "Essential" Evidence That the FDA Would Consider

Becker and Iwach's opinions regarding NIAs fail the *Daubert* standard for the additional reason that they failed to consider existing clinical data related to the NIAs that the FDA would have required for FDA approval of NIAs. Becker opines that the FDA would have found the alternative design "acceptable" and would not have required any additional clinical trials in doing so. (Ex. 69 (Becker Rpt.) ¶¶18-20.) Thus, Becker opines that Ivantis could have commercialized the alternative designs on the same schedule as the commercialized Hydrus.[6] (*Id.*) But Becker's opinion assumes that the clinical trial on the commercialized Hydrus would support an application

[6] Becker and Iwach identify two alternative designs, one that has as the only change a single radius of curvature and a second that has both a single radius of curvature *and* a change to the number of windows in the stent. (Ex. 69 (Becker Rpt.) ¶¶71, 74; Ex. 70 (Becker Tr.) 37:22-39:15.) The arguments in this motion address the reliability of opinions regarding any alternative that has a single radius of curvature, which both do.

to the FDA for the alternative design. To try to fill this void, Ivantis proffers Iwach to opine that the relevant changes to the commercialized Hydrus were "minor" and would have no material impact on the safety, efficacy, or functionality of the device. (Ex. 13 (Iwach Reb.) ¶¶223-225, 232.)

1. Background: The Infringing Hydrus and the Early Alternative Design

The infringing Hydrus has a dual radius of curvature. (Ex. 13 (Iwach Reb.) ¶226.) One portion has one radius of curvature, but a second portion has a tighter radius of curvature so that part of the Hydrus extends outside of Schlemm's canal. Ivantis commercialized the infringing dual-radius Hydrus design. (*See* Ex. 69 (Becker Rpt.) ¶71; Ex. 13 (Iwach Reb.) ¶226.)

(Ex. 69 (Becker Rpt.) ¶72; Ex. 13 (Iwach Reb.) ¶240.) As part of that effort, (Ex. 72 (Becker Dep. Ex. 11) at IVANTIS_SS_00452592.) (*Id.*)

2. Becker and Iwach Ignored the Information Most Important to Evaluating the NIAs

Rule 702 requires that an expert base any opinion "on sufficient facts or data." Fed. R. Evid. 702(b). Rule 702 "contains no exception to these requirements, so if they are not satisfied, an expert cannot testify before the 'trier of fact.'" *UGI Sunbury LLC v. A Permanent Easement for 1.7575 Acres,* 949 F.3d 825, 832 (3d Cir. 2020). The Federal Circuit has advised trial courts to "proceed with caution in assessing proof of the availability of substitutes not actually sold during

the period of infringement" because "[a]fter all, the infringer chose to produce the infringing, rather than non-infringing, product." *Grain Processing,* 185 F.3d at 1353.

a. Clinical Data on the Alternative Design is Critically Important—Including to the FDA

Becker admitted the importance of **clinical** data to the FDA process: "[c]linical experience with a medical device is essential for understanding product performance. The FDA regulatory process has always relied on clinical experience over bench testing and animal models to substantiate safety and effectiveness of medical devices." (Ex. 69 (Becker Rpt.) ¶ 50.) For an implanted device like the Hydrus, Becker described clinical experience as "particularly important" because "bench testing and animal models alone cannot be relied on to replicate or predict clinical performance." (*Id.*, ¶ 51.) An applicant cannot pick and choose what clinical data to submit. (*Id.* (stating that FDA "relies on **all** of the accumulated experience with the device.") (emphasis added).) Rather, "PMA applications not only provide data on the pivotal trial to support safety and effectiveness **but are also required to include other relevant clinical studies of the device**, and published literature." (*Id.* (emphasis added).)

If Ivantis had sought approval for the single-radius design, the FDA would have required Ivantis to submit any clinical data that it had on that design, as Becker admitted:

> Q. If [Ivantis] intended to go back and change the design that would be commercialized to a single radius design, would you expect any information on prior studies with the single radius design to be submitted to the FDA?
>
> A. **Well, certainly, yes, if there is clinical experience with previous – if there is clinical experience with it, yes.** Also, there may be – and I would expect that work to be available in the design history file for FDA review when they come for inspection.

(Ex. 70 (Becker Tr.) at 28:8-17 (emphasis added); *see also id*. at 99:9-22.) And the FDA would want to see that clinical data in deciding whether to approve a single-radius design or require additional clinical trials. (*Id.*; *id.*, 99:23-100:15, 87:8-88:5.)

b. [redacted] (Ex. 72 (Becker Dep. Ex. 11) at IVANTIS_SS_00452592; Ex. 70 (Becker Tr.) 99:9-12.) [redacted] (Ex. 72 (Becker Dep. Ex. 11) at IVANTIS_SS_00452592.) [redacted] (Ex. 70 (Becker Tr.) 82:5-16 [redacted]), 86:21-87:7 ([redacted].) Nor could Becker say that Iwach [redacted], (Ex. 70 (Becker Tr.) 91:25-92:8), and Iwach's expert report neither [redacted]. (Ex. 7 (Iwach Tr.) 245:17-246:9.) [redacted]:

[redacted]

(Ex. 70 (Becker Tr.) at 92:20-25.) This admission is fatal to both Becker and Iwach's opinions. [redacted] *See Pugh v. Community Health Systems, Inc.,* No. 5:20-cv-00630-JMG, 2023 WL 3361166, at *12 (E.D. Pa. May 10, 2023) ("[E]xclusion of proffered testimony is warranted where the expert fails to address evidence relevant to his or her conclusion." (alteration in original)

(quoting *Daniels-Feasel v. Forest Pharms., Inc.*, No. 17 CV 4188-LTS-JLC, 2021 WL 4037820, at *5 (S.D.N.Y. Sept. 3, 2021))). They did not, and offering any opinion about what the FDA would do is mere speculation.

3. [redacted]—the "clinically equivalent" lynchpin for Becker's opinion is supported by mere *ipse dixit* of Iwach. *See Hoefling v. U.S. Smokeless Tobacco Co., LLC*, 576 F. Supp. 3d 262, 275 (E.D. Pa. 2021) ("Neither *Daubert* nor Rule 702 require the Court to admit an expert's opinion that is 'connected to existing data' solely by the expert's '*ipse dixit*.'") (quoting *Gen. Elec. Co. v. Joiner,* 522 U.S. 136, 146 (1997)).)

The entire basis for Becker's opinion that the single-radius design would be "acceptable" to the FDA is that the single-radius design and the commercialized Hydrus are "clinically equivalent"—meaning "a design that would not in any material way have a different functionality, safety or effectiveness." (Ex. 69 (Becker Rpt.) ¶3; Ex. 70 (Becker Tr.) 42:21-25.) Becker admitted that she has no opinion on what the FDA would do if the single-radius design was not "clinically equivalent" to the commercialized Hydrus. (Ex. 70 (Becker Tr.) at 43:20-23.) Becker did nothing to determine whether the single-radius design and the commercialized Hydrus were "clinically equivalent." (Ex. 70 (Becker Tr.) 43:1-11.) She relies wholly on Iwach for that. Iwach opines that the change in the commercialized Hydrus from a dual-radius design to a single-radius design is "minor." (Ex. 13 (Iwach Reb.) ¶225.) He also claims that the change "would have no meaningful effect on the functionality, efficacy, or safety of Hydrus." (*Id.* ¶232.)

[redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

4. The Evidence Cited By Iwach and Becker [redacted]

The evidence cited by Becker and Iwach to support the claim of "clinically equivalent" does not render their opinions reliable. As Becker admits, other experts would not rely on such evidence to show the FDA that the two devices have the same safety and efficacy profiles.

a. The [redacted] are Irrelevant

Iwach cites [redacted]

First, [redacted]

[redacted]—provide no basis to reach any conclusion that the two designs are "clinically equivalent."

b. The [redacted] Opinion

Becker and Iwach cite [redacted]. (Ex. 69 (Becker Rpt.) ¶72 (citing Ex. 13 (Iwach Reb.) ¶240); *see also* Exs. 77 and 78 (Becker Dep. Exs. 4, 5).) Again, neither of these studies are reliable evidence of "clinical equivalence" for safety or efficacy. [redacted] (Ex. 13 (Iwach Reb.) ¶240; *see* Section XII.B.4.a above.) [redacted]

[redacted]. (Ex. 77 (Becker Dep. Ex. 4) [redacted]); Ex. 78 (Becker Dep. Ex. 5) [redacted] Thus, these two studies offer no basis for an opinion regarding the safety or efficacy of the single-radius design after implantation, and do not support "clinical equivalence."

c. The Risk Management Report is Not Based on the Clinical Data

Finally, Becker and Iwach rely on an Ivantis "Risk Management Report" ("RMR") to support their "clinically equivalent" opinion. (Ex. 79 (Becker Dep. Ex. 8).) [redacted] Iwach and Becker have no idea whether the actual clinical experience with the single-radius design confirms or refutes the assessments in the RMR.

In sum, none of the evidence that Becker and Iwach cite for their opinions is sufficient to show that the single-radius design and commercial Hydrus are "clinically equivalent." Thus, all that remains is Iwach's statement that because he characterizes the differences between the two designs as minor, he thinks they are clinically equivalent. That *ipse dixit* would not be good enough for the FDA, which would demand to review the clinical data, and is not good enough for the courts. *See Hoefling,* 576 F. Supp. 3d at 275 (quoting *Joiner,* 522 U.S. at 146.) Defendants'

failure to provide its experts the clinical data it had for alternative designs is not only highly suspicious, but fatal to its experts' opinions. The Court should exclude Drs. Becker and Iwach's opinions regarding the allegedly non-infringing alternatives.

B. The Opinions of Dr. Becker, Dr. Iwach, and Mr. Meyer Ignore the Law

When considering the availability of a non-infringing alternative, the time clock for designing around asserted patents starts at the time of first infringement. Defendants' experts impermissibly attempt to rewrite history to minimize damages by assuming design around efforts on non-infringing alternatives would have begun in 2011 or 2012 instead of in August 2018.

1. The Availability of Non-Infringing Alternatives is Evaluated as of the Date of First Infringement, Which Is August 2018

Damages for patent infringement can include a patentee's lost profits and a reasonable royalty for use of the invention. *See Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1157 (6th Cir. 1978). The availability, or not, of non-infringing alternatives is relevant to both lost profits and reasonable royalty damages. *See Panduit*, 575 F.2d at 1156; *see also Prism Techs. LLC v. Sprint Spectrum L.P.*, 849 F.3d 1360, 1376 (Fed. Cir. 2017). Under either damages approach, the law is that the availability of non-infringing alternatives not already on the market is assessed beginning at the date of first infringement—here, August 2018—and no earlier.

a. Lost Profits Damages

In *Grain Processing Corp. v. Am. Maize-Prods. Co.*, the Federal Circuit held that the district court "erred in refusing to award lost profits based on a noninfringing substitute that was not available **at the time of infringement**." 108 F.3d 1392 (table), 1997 WL 71726, at *1 (Fed. Cir. Feb. 20, 1997) (emphasis added). That decision emphasized that "the law is clear-to be an acceptable noninfringing substitute, the product or process must have been available or on the

market **at the time of infringement**." *Id*. at *2 (emphasis added); *see also Grain Processing Corp.*, 185 F.3d at 1348 (Fed. Cir. 1999) (same).

More recently, in *Apple, Inc. v. Samsung Elecs Co.*, the Northern District of California addressed whether the starting point for actions that the infringer could have taken to design around the infringed patents is the date of first infringement or another date. No. 11-cv-01846, 2013 WL 5958172, at *2 (N.D. Cal. Nov. 7, 2013). After examining *Grain Processing*, it held that (i) "the question of *when* one must begin to consider the *possibility* of design arounds is a question of law" (emphasis in original), and (ii) "an accurate reconstruction of the hypothetical market that would have existed 'but for' an infringer's infringement must take into account actions the infringer could have taken in lieu of infringing, including designing around the patented intellectual property, **as of the date of first infringement**. **Any other start date arbitrarily excludes economic conditions that are relevant in reconstructing this 'but for' world**." *Apple*, 2013 WL 5958172, at *6-7 (emphasis added). *See also Janssen Biotech, Inc. v. Celltrion Healthcare Co. Inc.*, 239 F. Supp. 3d 328, 331 (D. Mass. 2017) (same).

b. Reasonable Royalty Damages

A common approach for determining reasonable royalty damages is the hypothetical negotiation approach, which attempts to ascertain the royalty the parties would have agreed had they successfully negotiated. *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1324–25 (Fed. Cir. 2009). The date of the hypothetical negotiation is the date that infringement began. *Applied Med. Res. Corp. v. U.S. Surgical Corp*., 435 F.3d 1356, 1363–64 (Fed. Cir. 2006). If the availability of an alleged NIA is at issue, the same rule applies—actions the accused infringer could have taken to design around are presumed to begin on the date of first infringement, *i.e*., the date of the hypothetical negotiation. In *AstraZeneca AB v. Apotex Corp.*, the Southern District of

New York addressed an argument virtually identical to Defendants'—that Apotex could have developed an alternative, non-infringing formulation that would receive FDA approval as a bioequivalent form of the drug omeprazole. 985 F. Supp. 2d 452 (S.D.N.Y. 2013) ("*AstraZeneca*"), *aff'd in relevant part*, 782 F.3d 1324, 1334-35 (Fed. Cir. 2015) ("*AstraZeneca II*"). Apotex suggested that, at the hypothetical negotiation, "it should be assumed that Apotex would have begun developing a non-infringing alternative formulation in 2000, when it filed its ANDA." *Id*. The court rejected that assertion, concluding, "**Apotex's argument contradicts settled law**." *Id*. (emphasis added). The court reasoned, "[t]he hypothetical negotiation approach to determining a reasonable royalty posits that a negotiation occurred at a particular time, which in this case has been stipulated to be November 2003 [i.e., the hypothetical negotiation date]. . . . This framework is incompatible with Apotex's suggestion that it should be assumed to have been pursuing noninfringing alternatives as early as 2000." *Id*. at 500-01.

The *AstraZeneca* court's holding followed the reasoning in *Hanson v. Alpine Valley Ski Area, Inc.*, 718 F.2d 1075, 1081-82 (Fed. Cir. 1983). In *Hanson*, the Federal Circuit rejected the argument that a royalty was unreasonable because it exceeded the cost of a non-infringing alternative, observing that "Alpine could have avoided infringement, and paying royalties therefor, by purchasing non infringing machines. . . . It chose, however, to purchase and use [the] infringing machines. Having followed that course, it cannot invalidate an otherwise reasonable royalty on the claim that by hindsight it would have been better off if it had purchased the non-infringing . . . machines." *AstraZeneca*, 985 F. Supp. 2d at 501 (quoting *Hanson*, 718 F.2d at 1081-82). The *Apotex* court interpreted the *Hanson* decision to mean that "**[t]he hypothetical negotiation is hypothetical in the sense that the negotiation itself is imaginary, not in that it allows the parties to construct an entirely imaginary world that ignores the facts as they existed at the**

date of infringement. Those facts show that Apotex did not have a non-infringing alternative formulation ready and waiting. That this was the situation in which Apotex found itself in November 2003 is one of the most salient features of the negotiating dynamic in this case and may not now be ignored." *Id*. (emphasis added).

The Federal Circuit affirmed that portion of the decision. *AstraZeneca II*, 782 F.3d at 1334-35. It agreed that the date to begin designing around the patent was the date of first infringement (not earlier) and held that "it was proper for the court to hold that the difficulties Apotex would have encountered upon attempting to enter the omeprazole market with a non-infringing product are relevant to the royalty rate a party in Apotex's position would have been willing to pay for a license to Astra's patents." *Id*. *See also Shure Inc. v. ClearOne, Inc.*, C.A. No. 19-1343-RGA-CJB, 2021 WL 7209740, at *6 (D. Del. Oct. 5, 2021) (denying *Daubert* motion after concluding that damages expert correctly assessed costs of implementing an NIA beginning on the date of the hypothetical negotiation). Thus, for lost profits or a reasonable royalty calculation, Defendants' experts had to assume that Ivantis would have begun designing around the Asserted Patents in August 2018—the date of first infringement—and no earlier, but they ignored the law.

2. Becker, Iwach, and Meyer All Assume that Ivantis Would Have Begun Designing Around the Asserted Patents in 2012—Not 2018 As Required

In this lawsuit, the date of first infringement, and the hypothetical negotiation, is indisputably August 2018. (Ex. 67 (Jarosz Op.) ¶110; Ex. 66 (Meyer Reb.) ¶¶40, 133.)[7] That makes the date for beginning to design around the Asserted Patents also August 2018. *Apple, Inc.*, 2013 WL 5958172, at *6-7; *AstraZenenca*, 985 F. Supp. 2d at 500-501.

[7] On August 10, 2018, the FDA approved Ivantis' premarket approval application for the Hydrus. (D.I. 77, ¶42.) Defendants did not commercially manufacture, sell, offer to sell, or use the Hydrus prior to FDA approval. (Ex. 71 (Second Supplemental Responses to Sight Sciences' Second Set of Interrogatories) at 4-5.)

The Becker and Iwach opinions, on which Mr. Meyer relies, assume design around efforts began in 2011 or 2012. Dr. Becker was asked to offer opinions as to the regulatory process required for FDA approval of alternatives had Ivantis begun developing them in 2012. (Ex. 69 (Becker Rpt.) ¶¶3, 20, 77, 78, 80, 82, 84, 90 (emphasis added); *see also* Ex. 70 (Becker Tr.) 100:22-105:21.) Dr. Iwach similarly assumes that Ivantis began designing around in March, 2011, "before the asserted patents began issuing in October, 2012." (Ex. 13 (Iwach Reb.) ¶229; *see also* ¶258 (offering same opinion for the two window design NIA).)

Mr. Meyer's opinions concerning (and relying on) NIAs exclusively depend on Dr. Becker's and Dr. Iwach's opinions and assume that Ivantis began to design around the Asserted Patents in the 2011-2012 timeframe. (Ex. 68 (Meyer Tr.) 94:7-23 ("Q: And so, you're assuming, Mr. Meyer, for the purposes of your report, that the alleged non-infringing alternative designs to the – to the commercial Hydrus® version were available **and also would have been implemented in the but-for world, beginning in 2012. A: I'm making that assumption.** … I then accepted Dr. Becker's position that in 2012, the path would have been taken to implement one of those alternative designs.") (emphasis added); Ex. 66 (Meyer Reb.) ¶105; ¶160 ("As addressed above, acceptable non-infringing alternatives were available to Ivantis by 2011. … I understand from Dr. Becker that implementing the identified non-infringing alternative Hydrus designs **in this time period** would not impact Hydrus's actual August 2018 launch date.") (emphasis added); *see also id.*, ¶¶ 21(a), Table 3, 22, 137, 153, 154, 155, 156, 159, 161, 162, 248, 249, 250, Table 18, 261, 268, Attachments 5.1, 5.2, 5.3.)

Mr. Meyer concludes that Ivantis could have had an alleged NIA on the market or readily available in August 2018—*i.e.*, at the same time that the accused Hydrus was launched in the real world. (Ex. 66 (Meyer Reb.) ¶¶22, 160.) The problem with these opinions is that no NIA was

actually on the market or "readily available" at that date. *See Grain Processing Corp. v. Am. Maize Prods. Co.,* 185 F.3d 1341, 1353 (Fed. Cir. 1999). Because none was already on the market and FDA-approved for commercial sale, Ivantis bears the burden to prove that Ivantis could commercialize an alternative design "readily." *See Siemens Med. Sols. USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.,* 637 F.3d 1269, 1288 (Fed. Cir. 2011). According to Mr. Meyer, six to nine months of additional research, development, and testing would have been necessary to design-around the Asserted Patents. (Ex. 68 (Meyer Tr.) 105:21-107:24 (single radius Hydrus required additional six months of research and development); Ex. 68 (Meyer Tr.) 119:20-121:19 (single radius two window Hydrus required additional nine months of research and development).) And Dr. Becker opined that regulatory approval was required before an NIA could be on the market or readily available and that would have required additional delay. (Ex. 69 (Becker Rpt.) ¶90 ("had Ivantis implemented an alternative design after the FDA approval of the Hydrus, at most, Ivantis would have needed to file a 180-day PMA supplement to the originally approved PMA.").) To overcome the reality that any NIA required research, development, testing, and FDA approval before it was on the market or readily available, Defendants' experts ignored the law by assuming that Ivantis would have begun designing around the Asserted Patents in 2012. But Ivantis did not pursue NIAs in 2012, so its experts cannot pretend design around efforts began earlier than August 2018.

Dr. Becker, Dr. Iwach, and Mr. Meyer all wrongly conclude that Ivantis would have had a non-infringing alternative on the market or readily available in August 2018 because they wrongly assume that Ivantis would have begun design around efforts six years earlier. *AstraZeneca,* 985 F. Supp. 2d at 501 ("[t]he hypothetical negotiation is hypothetical in the sense that the negotiation

itself is imaginary, **not in that it allows the parties to construct an entirely imaginary world that ignores the facts as they existed at the date of infringement**.") (emphasis added).

The Court should exclude the opinions of Dr. Becker and Dr. Iwach concerning NIAs to the extent they assume design around efforts began at any time earlier than August 2018. (*See* Ex. 69 (Becker Rpt.) ¶¶20, 77, 78, 80, 82, 84, 90; Ex. 13 (Iwach Reb.) ¶¶229, 258.) *See Minerva Surgical, Inc. v. Hologic, Inc.*, No. 18-00217-JFB-SRF, 2021 WL 3048447, at *6 (D. Del. July 20, 2021) (citing *Intell. Ventures I LLC v. Xilinx, Inc.*, No. 10-1065-LPS, 2014 WL 1814384, at *3-4 (D. Del. Apr. 14, 2014) (striking opinion because expert's "understanding of the law is incorrect" and "renders his opinion unreliable")).

Because Mr. Meyer's opinions exclusively rely upon Dr. Becker's and Dr. Iwach's opinions, and because he solely calculates costs for implementing design arounds assuming a design-around start date in 2011 or 2012, the Court should additionally exclude his damages opinions relating to (or depending on) the availability of non-infringing alternatives. (*See* Ex. 66 (Meyer Reb.) ¶¶21(a), Table 3, 22, 105, 106, 137, 153, 154, 155, 156, 159, 160, 161, 162, 248, 249, 250, Table 18, 261, 268, Attachments 5.1, 5.2, 5.3.) *Minerva*, 2021 WL 3048447, at *6.

XIII. MOTION TO EXCLUDE EXPERT TESTIMONY OF STEPHEN KUNIN IN ITS ENTIRETY

Absent extraordinary circumstances, "judges in this District have a well-established practice of excluding the testimony of legal experts . . . ." *AstraZeneca UK Ltd. v. Watson Laby's, Inc.*, No. CA 10-915-LPS, 2012 WL 6043266, at *1 (D. Del. Nov. 14, 2012). No such extraordinary circumstances are present with the proposed testimony of Mr. Kunin—who holds himself out as an expert in U.S. patent law, policy, practice, and procedures. (*See* Ex. 80 (Kunin Reply) ¶12.) Indeed, because the testimony offered by Mr. Kunin will not be helpful to the trier of fact in determining any facts in issue, it does not "fit" the proceedings and should be excluded

in its entirety. *See In re TMI Litig.*, 193 F.3d 613, 670 (3d Cir. 1999) ("The expert's testimony must 'fit,' and admissibility depends, in part, on a connection between the expert opinion offered and the particular disputed factual issues in the case.").

Mr. Kunin's report is mischaracterized as a reply to Dr. Downs' Rebuttal Report regarding the validity of the Asserted Patents, and, more specifically, to Dr. Downs' statements noting the fact that several prior art references had been "considered" by the examiner during prosecution or had been found by the Patent Trial and Appeal Board (PTAB) to be "same as or substantially the same as" references that were "previously presented" to the Patent Office during prosecution of one or more of the Asserted Patents. (*See* Ex. 80 (Kunin Reply) ¶¶2, 64.) Mr. Kunin **for the first time in reply** summarizes his expected testimony as purportedly concerning the rules, policies and procedures of the PTO and PTAB, and the prosecution histories and four IPR proceedings associated with the Asserted Patents. (Ex. 80 (Kunin Reply) ¶¶19-21.) After discussing these file histories and IPR proceedings, Mr. Kunin opines that there was no evidence that six of the seven prior art references that Mr. Kunin addresses were "substantively reviewed" by the examiner when determining patentability of the Asserted Patent claims. (*See* Ex. 80 (Kunin Reply) ¶¶64, 74, 81, 85, 89, 92, 98, 116, 124; *see generally id.*, ¶¶62-125.) By "substantively reviewed," Mr. Kunin states that he meant "the claims must have been distinguished over the art in the record where the art was the basis of a rejection and where the rejection was withdrawn or overcome by an amendment, was distinguished in a notice of allowance, or was discussed during an examiner interview. (*See* Ex. 81 (Kunin Tr.) 71:19-72:1, 84:20-85:21); Ex. 80 (Kunin Reply) ¶61.)

Mr. Kunin's opinions that the Patent Office did not "substantively review" prior art references at-issue in this lawsuit are irrelevant and misleading because the U.S. Patent Office defined in a precedential decision when prior art has been reviewed during patent prosecution, and

Mr. Kunin's definition is inconsistent with the Patent Office definition. In *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020) (precedential), the PTAB held that "[p]reviously presented art includes art made of record by the Examiner, and art provided to the Office by an applicant, such as on an Information Disclosure Statement (IDS), in the prosecution history of the challenged patent." *Id*. at 7–8. Applying *Advanced Bionics*, the Patent Trial and Appeal Board has repeatedly held that an IDS citation alone is deemed previously presented to, and considered by, the Office. *Eyenovia, Inc. v. Sydnexis*, IPR2022-00963, Paper 7 at 10–11 (PTAB Nov. 8, 2022); *Fellowes, Inc. v. Treefrog Devs., Inc.*, IPR2020-01509, Paper 11 at 7–8, 17 (PTAB Feb. 22, 2021); *Ocado Grp. PLC v. Autostore Tech. AS*, IPR2021-00412, Paper 9 at 34–35 (PTAB July 21, 2021). Mr. Kunin fails to cite any post-*Advanced Bionics* decisions to substantiate his assertion that "[t]here is currently a split among PTAB panels regarding whether prior art that was not substantively applied against the claims of a patent application to show their unpatentability, such as prior art merely listed in an IDS or examiner search report, would be enough to issue a discretionary denial under Section 325(d)," despite having earlier acknowledged the currently controlling *Advanced Bionics* framework. (Ex. 80 (Kunin Reply) ¶¶49, 56-57.) Mr. Kunin's opinions should be excluded because they are inconsistent with and fail to apply the current Patent Office standard. *Minerva Surgical*, 2021 WL 3048447 at *6 (striking expert's opinion because expert's "understanding of the law is incorrect" and "renders his opinion unreliable").

Moreover, Mr. Kunin's opinions are not responsive to any opinions or disputed factual issues in this case. Neither Dr. Downs nor Plaintiff has asserted that any of these six prior art references were used as a basis for rejection or otherwise substantively discussed by the examiner in the file histories of the Asserted Patents. Indeed, many of Mr. Kunin's opinions are explicitly

conditional, stating, for example, he disagrees "to the extent Dr. Downs is opining that Stegmann had been substantively reviewed by the examiner." (*See, e.g.*, Ex. 80 (Kunin Reply) ¶124; *see also id*. ¶71.) Dr. Downs did not so opine, and the conditions (whether express or implicit) underlying Mr. Kunin's opinions are not satisfied. Thus, Mr. Kunin's surprise "reply," which provides opinions responding to manufactured hypothetical counterfactuals, is not helpful to the factfinder.

Further, Mr. Kunin's opinions that the PTAB's decisions denying institution of *inter partes* review "may have come out differently if [a] proposed rule change [as to how the Board exercises its discretion under 35 U.S.C. § 325(d)] had been codified at the time of the decision[s]" is potentially prejudicial speculation regarding counterfactual scenarios. (Ex. 80 (Kunin Reply) ¶¶60-61, 82, 94.) Mr. Kunin did not offer any opinions expressly disagreeing with the PTAB's findings or its application of the operative rules and guidelines when reaching its non-institution decisions. (*See, e.g.*, Ex. 81 (Kunin Tr.) 25:12-26:14, 28:3-6, 29:11-31:12.) Mr. Kunin's speculation about what the PTAB might have done had a different rule been in place when it decided not to institute is of no help to the factfinder, so these opinions should be excluded as well.

Finally, Mr. Kunin's testimony should also be excluded because of the risk that it will be misused to proffer impermissible legal conclusions regarding patent law, usurping the role of the Court, or to improperly imply that the examiner failed to do his/her job properly when issuing the Asserted Patents. Mr. Kunin's nominal focus on the practices and procedures of the PTO (*see* Ex. 80 (Kunin Reply) ¶¶19-61) is a Trojan horse for such impermissible opinions. For example, Mr. Kunin discusses the burden of proof of establishing invalidity of an issued patent, "regardless of whether the asserted prior art was 'considered' by the U.S. Patent Office during examination." (*See* Ex. 80 (Kunin Reply) ¶¶27, 69.) This is impermissible expert testimony on patent law. Mr. Kunin also offers opinions regarding the **average** workload of patent examiners and the amount

of attention and consideration **typically** afforded by an examiner to references under various circumstances, unmoored to the patents at issue here. Mr. Kunin's opinion improperly suggests that the PTO failed to do its job in this case and seeks to undermine the presumption of validity afforded to the Asserted Patents. (*See, e.g.*, Ex. 80 (Kunin Reply) ¶¶25, 33-36 ("Thus, 'considered' does not mean that the examiner actually looked at or studied the document in great detail, such as reading it line for line.").) This court has previously excluded such improper opinion testimony. *Shire Viropharma Inc. v. CSL Behring LLC*, No. CV 17-414, 2021 WL 1227097, at *18 (D. Del. Mar. 31, 2021) (citing *Commonwealth Sci. and Indus. Rsch. Org. v. Mediatek Inc*., No. 6:12-cv-578, 2015 WL 12806515, at *5 (E.D. Tex. June 29, 2015) (excluding testimony regarding quotas, mistakes, average hours worked on applications, and limited resources as impermissibly attacking presumption of validity and not tied to facts of the case)). The Court should exclude the testimony offered by Defendants' patent law expert, Mr. Kunin, in its entirety.

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CERTIFICATE OF SERVICE

I, Melanie K. Sharp, Esquire, hereby certify that on October 12, 2023, I caused to be electronically filed a true and correct copy of Sight Sciences, Inc.'s Opening Brief in Support of its Motions for Summary Judgment and to Exclude Expert Testimony with the Clerk of the Court using CM/ECF, which will send notification to the following counsel of record:

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